**National Food Processors Association**

**Food Industry Coalition for Implementation of the**
**Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

**1350 I Street, NW**
**Suite 400**
**Washington, D.C. 20005**

**Wednesday, August 28, 2002**
**1:30pm - 4:30pm**

**MEETING MINUTES**

Welcome and Introductions..... Richard N. Jarman
Vice President, Food and Environmental Policy
National Food Processors Association

Lloyd R. Lake
Director of Regulations and Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Leslye M. Fraser
Associate Director for Regulations
Center for Food Safety and Applied Nutrition
Food and Drug Administration

## OPEN DISCUSSION

### Registration Provision

Coalition initial comments:

- Industry goal is to give FDA the required information; but requests that FDA recognize need for flexibility (i.e., paper and electronic submissions)

- Industry requests that FDA allow corporations to register individual facilities within that corporation (i.e., allow parent corporation to act on behalf of subsidiaries)

- ? Industry prefers electronic registration but there is a need for paper registration as well.

- ? Industry recognizes and appreciates the flood of registrations in the beginning, but wants automatic registration number given once system is in place.

- ? If food is held at port of entry due to lack of registration, it must be held in a way that the food remains marketable.

- ? Industry encourages FDA to not use food categories, as they pose problems as to what is covered in 170.3 and what is not.

- ? For effective and implementation dates, FDA needs to consider the time lag of how long it will take the FDA to get a response out.

Bob Lake initial comments:

- ? We may get information from CIA that a particular food category/product is targeted. We would need to have food/product category information to pin point which facilities may be involved.

- ? The FDA favors the electronic system that once all boxes are filled in, you would receive the registration number/immediate confirmation of the registration.

- ? Bill Hubbard's group is working on the IT portions of electronic registration.

- ? The FDA has a very strong desire to be in a position to receive registrations and to be clear about the information we need.

Industry: Are we looking at using outside contractors?

Bob Lake: That decision has not been made.

Leslye Fraser: With regard to industry's comment regarding delay of effective date, the statute is clear that facilities must be registered by 12/12/03.

Industry: Industry recommends that the FDA avoid the idea of instantaneous compliance requirements to get ahead of the game.

Leslye Fraser: The FDA is working on getting the regulation out 2 months before the deadline so as to have time to receive registrations before the effective date.

Industry: The FDA should consider having a compliance provision in the regulation. If tens of

thousands of firms try to register at the same time it could crash the system. The FDA should not be taking enforcement actions in this case.

Industry: The FDA should defer the issue of product categories in 170.3. Those categories are decades old. The products do not neatly fit. There is not time to amend 170.3 and get the registration regulation done at the same time. Concern is that if you put the categories in now, the regulation will not work. Companies will have a registration turned down because they cannot determine which category in 170.3 is the correct one for their products.

Bob Lake: The FDA is considering the nature of the business as being helpful. Having no information on product type makes the provision of limited value.

Industry: The product type by storage location or by company gets very complex in terms of distribution warehouses to be able to identify all product categories at that facility.

Industry: What about facilities that exclusively engage in R & D?

Leslye Fraser: The statute says engaged in food for consumption in the United States.

Industry: One thing to consider as far as consumption in the United States, is it in the channels of trade?

Industry: Who is responsible to register?

Leslye Fraser: The statute places the responsibility on the owner/operator in charge of the facility. Each facility will have the responsibility.

Industry: The statute is different on the pharmaceutical side. We would like to see the FDA make this registration regulation better and not as confusing as the drug regulation.

Leslye Fraser: What do you see as effective ways to get this information out, especially to importers?

Industry: The FDA should be able to inform in different languages and should work with foreign governments and embassies.

Bob Lake: In addition to the domestic outreach, the FDA recognizes the need for international outreach. Any ideas on how to get the word out is appreciated.

Industry: The Foreign Act Service already has in place ways to distribute the information. There is a website that has questions and answers that can be distributed to foreign agencies. Foreign embassies also should be included in the outreach efforts.

Leslye Fraser: The FDA had an embassy briefing that went well. Most questions focused on registration and prior notice. There were concerns about outreach discussed.

Industry: Has the FDA looked at this with Commerce and other federal agencies to identify what WTO issues are raised?

Bob Lake: Yes. The FDA has had external and internal conversations and has met with state people. We are working through these issues. When proposals publish, we will have to do outreach and get feedback.

Industry: Electronic submission issues will have to be handled sensitively due to discrimination issues with developing countries.

Industry: Foreign facilities have a larger burden as they have to appoint a U.S. agent. The FDA should consider that foreign facilities have this larger burden than domestic facilities.

Bob Lake: It is the FDA's desire to get the system up and running and get the information out on the street regarding what is required well before the effective date of the regulation.

Industry: The FDA should be flexible in the unique situation that someone did not know about the requirements before enforcement actions are taken.

Bob Lake: The FDA promises to read all comments in by August 30, 2002. Everything else will be read with the comments to the proposed rules.

Industry: With regard to foreign versus domestic facilities, when a product comes to a port of entry, it will not be obvious if this particular facility was supposed to register. How will you know when the product arrives at the border if it comes from a facility that was supposed to register or not?

Bob Lake: The FDA is considering this issue.

Industry: It will come down to prophylactic registration. Facilities will register anyway so as to avoid any delays/problems at the border. The plant has not the slightest idea of what happened to their product. The exporter is not going to track down the foreign facility that made the product to see if it registered.

Industry: If the FDA is not very flexible with the registration requirements in the beginning, on 12/13/03 there will be imports stacked up at the borders.

**Recordkeeping Provision**

Coalition initial comments:

- The key thing is what information allows the FDA to identify the physical location of the previous source and subsequent recipient.
- Industry encourages the FDA to consider flexibility in using documents already available to satisfy these requirements.
- The FDA is encouraged to look at existing business practices and then determine what additional information, if any, is needed.
- The FDA is encouraged to consider time factors and things that influence the time in which a business can respond (i.e., the start up money a business needs to keep these records).
- The FDA needs to consider the precision with which individual sources can be identified (i.e., commingled ingredients).
- The FDA is encouraged to stay away from requiring a specific contact person that may change repeatedly over a period of time.
- Bills of lading, purchase orders, etc., are all existing records that may satisfy these requirements.
- There are situations where someone may have custody and control of raw materials, but do not own it. Previous sources and subsequent recipients may not always be someone with ownership rights.
- The ability to link incoming products and ingredients with outgoing products and ingredients is difficult.
- The FDA should consider exempting certain businesses (no suggestions at this time).
- Industries interpretation of "packaging" does not include going beyond the supplier of the food contact package.
- The FDA should consider the size of business and possible exemptions. The coalition has had no consensus on which businesses to exempt but suggests the FDA consider giving phase-in dates on smaller businesses.
- Industry feels that while different record retention is appropriate for certain foods but

does not want to add undue degree of complexity in terms of knowing what the appropriate maintenance time may be.

? The statute says in order to identify the "immediate previous sources" which is plural, therefore companies should be able to identify all possible sources for that ingredient, not the specific source.

Bob Lake initial comments:

? The intent of the provision and what the Department of Health and Human Services was advocating is to have the information that allows the trace back and trace forward to work. What is kept is the important part, not necessarily how the records are kept. Having the right information that is readily available are the important elements. We are interested in tracing a public health problem that has already identified itself and we want to get to the source. It is an unresolved issue as to what is needed. The FDA is working on this.

Industry: The information needed – is it more than the name, address and article of food?

Bob Lake: We are thinking it is beyond that. We need to have information that allows us in a reasonable period of time in an emergency situation to identify the source. If there is a major outbreak and we cannot complete the chain for tracing then we have a major problem.

Industry: Is it physical possession or legal title? What event triggers the records requirement? There will be situations where someone will have physical custody but not ownership rights to the food, (i.e. when warehouses hold food.)

Leslye Fraser: The statute says those that manufacture, process, pack, etc. We are still interpreting the statute to decide if having ownership rights or just custody carries out the intent.

Industry: How does the FDA interpret "immediate"; does that include transporter?

Leslye Fraser: We are looking at how the food moves along the chain and how transporters fit into the chain.

Bob Lake: The transporter is acting as an agent for someone else like the buyer or seller.

Industry: There are loads of grain products that are commingled about 17 different ways before it ever even gets to the processing facility. Industry needs guidance on what FDA wants here.

Bob Lake: Such information would include who the suppliers are, when did you get the material from that supplier, what products are coming in from what sources.

Industry: Measuring the success of this particular provision in terms of commingling would allow for more specificity than FDA currently requires.

Bob Lake: If we end up with a regulation that does no more than we are doing today than that is not a success. If you do a comprehensive analysis of all food businesses, some are doing a better job than others. If we look at what the better companies are doing – shouldn't everyone else maybe step up a bit?

Industry: What do we mean a better job? If a small bread maker, he only has one supplier. If larger bread maker, maybe 5 suppliers. FDA doesn't want the names of all five suppliers? This chain of distribution regulation is not the place for this. Better under GMP rulemaking. This is not what Congress has in mind here. They wanted to make traceback and traceforward possible at any step in the chain. Industry should be able to give all possible sources and not the specific source. The rule ought not prescribe the form but merely what information needs to be made available, such as the name and address of the source.

Bob Lake: Telling us 7 suppliers is not nearly as good as saying "last week these two suppliers were used."

Industry: Industry cannot tell you that the flour they got on the 3rd of August was used in pizza crust on August 7th.

Bob Lake: You will need to know where did that pizza crust go? What is the likelihood that the flour that came in on this date went to all of your customers?

Industry: If you go back to the company, it is in their best interest to keep records to narrow implicated parties – but here is not the rule to require this. GMP's are the place for this.

Bob Lake: This rule is about what records need to be kept. We have not worked this out yet.

Industry: For example, you have a 20,000 pound silo filled with flour going to 5 separate lines making pizza crust that had 3 different suppliers. Industry cannot tell you exactly which supplier made that pizza crust. With these commingled silos, especially liquid, there is no way of telling the specific supplier.

Bob Lake: There may be many situations where there is no better way to do it. It is in everyone's interest to be thinking about this. Products are recalled because no-one can pinpoint the problem. If there is a foodborne outbreak, we need to be able to pinpoint where

the suspect product is.

Industry: What about trade secret information? Specifically recipes – are formulations included? They are intellectual property.

Bob Lake: Recipe is the combination of the ingredients and the amounts. We are going to need to know what the ingredients are.

Industry: We would like to have clarification of what is considered a "recipe" in the document. Would the ingredients in spices be included?

Bob Lake: Trying to do traceback to a source would also require knowing the ingredients in spices.

Industry: What about retail stores that also make products on-site? It is assumed that you would not require records to be kept of the consumer buyer.

The FDA is urged to understand the costs and burdens associated with this rulemaking. Can we expect a robust and full explanation from economics at the proposed rule stage?

Bob Lake: We do intend and are required to look at costs and paperwork implications, etc. Our economists may be in touch with you to probe into existing practices, etc.

Leslye Fraser: We are looking for the data to back up whatever proposals you have.

Nega Beru: Any comments on accessibility and availability of records?

Industry: Might want to take a look at LACF regulations to see how they are modeled. Depending upon the scope, if you are asking for each source this may be a more difficult regulation to comply with. Retailers records are all over the map. Some are electronic. Industry would appreciate flexibility here.

Leslye Fraser: The balancing between being flexible and not waiting days or weeks for the required information is something the FDA currently is considering.

Industry: LACF speculated emergency situations. We should look at this.

As far as access to the records, will the standard be included in the regulation?

Bob Lake: This issue is yet to be resolved.

Industry: The access question involves record availability not establishment and maintenance of

records.

Leslye Fraser: If we have met the trigger/standard we are in the access mode. What is reasonable to expect as far as time frame for getting these records?

Industry: Getting the information may come before getting the record. Isn't that the focus? It should be ok to have rapid access to the information versus being able to produce the actual record itself.

Is the FDA considering confidentiality of the records and how FOI plays into this?

Bob Lake: Yes. Confidentiality considerations are current under way within the FDA.

**Prior Notice Provision**

Coalition initial comments:

?? Industry is interested in the least possible disruption of trade.

?? A seamless integration into existing systems is needed. The requirements for prior notice could be integrated into Customs' ABI system. The ABI information is consistent with prior notice requirements except for the grower information.

?? Linking into the OASIS system: system enhancements will need to be made.

?? The definition of "article of food" needs to be defined so that it matches the product description/bill of lading.

?? Grower information: FDA should not trigger a new duty to find grower information because it is difficult to determine.

?? Identification of responsible party: this is most likely the importer of record; Customs has a flexible definition of "importer of record" in their regulations.

?? Electronic transmission of information: this mode is convenient, especially if the submitter is provided with an immediate response of information received.

?? FDA is urged to institute 24-hour coverage, 7-days a week at the ports.

?? Minimum time periods: variables should be limited and based on mode of transportation. Notification should be kept as short as possible. Flexibility is needed to accommodate problems, such as weather; flexibility is needed also when modifying prior notice information.

?? FDA should consider Customs' CTP system, a process for identifying low-risk importers.

?? Failure to comply: hold versus administrative detention. If a product is held for failure to comply, the hold should last only until the information requirements are met.

Bob Lake's initial comments:

?? FDA has had many meetings with Customs. There is value in linking with existing systems.

?? The "hold" in prior notice is restricted to that and is not related to administrative detention.

?? The prior notice time we have now is zero. This probably is not the right answer.

?? Considering the modes of transportation is a good, obvious approach.

Leslye Fraser's initial comments:

?? FDA meets with Customs on a weekly basis. Customs' new system will not be ready by our publication goal of October 12, 2003. We are now in discussions regarding how we can use the current system to meet our needs. The notice being provided now is at the port of entry—this is not the prior notice required by the statute. We are looking into how the current system can be modified to meet the new requirements. In this sense, we simply cannot piggy-back on the existing systems.

?? Mary Ayling added: Customs also has a requirement to give their filers 60-day notice if any changes are being made to their (current) system.

Industry: Will the information come to a central place or port?

Mary Ayling: The system is like a central place.

Industry: Will it be electronic?

Bob Lake: That is the ideal. We aren't there yet.

Industry: OASIS is integrated into the ABI system. The current OASIS screen captures everything required in prior notice except "grower if known." Why is this such a big deal?

Mary Ayling: The data elements are not what they seem to be, e.g. manufacturer, country of origin, etc.

Leslye Fraser: There are 2 issues: 1) current information in OASIS, and 2) how the Customs' database is set-up now. When information is provided at the border, that is not prior notice—we want the information before entry.

Industry: Is it possible to use the advance manifest?

Leslye Fraser: That is one of the items under discussion.

Bob Lake: Prior notice is more complicated than at 1st glance. However, we are optimistic that we will be able to work something out.

Industry: Will this require 2 parallel systems?

Bob Lake: We are hopeful that prior notice can be folded in, such that only 1 filing would be needed.

Industry: A prior notice filing and an OASIS filing can be done simultaneously?

Mary Ayling: We are working on this—a combination of this.

Leslye Fraser: We are looking at a system that uses information you are used to giving at an earlier time.

Industry: Air cargo and certifying "wheels up." Is this being considered?

Industry: Quota-class merchandise requires a different kind of entry—one cannot make entry until the vessel enters port.

Leslye Fraser: That is why we can't simply use Customs' existing system; we are not just asking for the same information earlier.

Bob Lake: We are committed to making the deadline. This provision has hammer/default provisions.

Leslye Fraser: Our ideal plan is to use Customs' system, but we need a back-up plan. We may have to use an interim system and go back to look at a new system once Customs' new system is operational.

Industry: Take for example a truck traveling from Canada to the U.S.—can bonded warehouses be used?

Mary Ayling: We are looking into this. Trucks are different because they can turn around. We are looking into pre-filing.

Industry: What kinds of comments are most helpful to you?

Mary Ayling: What kinds of things do you think can be flexible? Intended ports of entry? Timeframes and when information can be updated?

Leslye Fraser: We heard from other stakeholders that FDA should be flexible with quantity.

Industry: Piggyback on existing Customs system and be flexible in adding on to that system.

Bob Lake: We need particulars on where flexibility is needed.

Leslye Fraser: We are looking into being flexible, while meeting statutory objectives.

Amber Jessup: From an economist's standpoint, we need to know how what we are requiring you to do would be different from what you do now.

Industry: How specific do you expect prior notice to be, e.g., 5 trucks are expected at 4:00 PM?

Industry: A person probably would want to give notice far in advance.

Leslye Fraser: An issue we are considering is although we can't require more than 5 days notice, can we accept it if it is voluntarily submitted?

Industry: Customs' requirement is that notice could not be given more than 5 days ahead of time. Prior notice should be tied to Customs' system.

Mary Ayling: Is there any comment about the responsible party being the U.S. agent?

Industry: I don't see why not.

**Administrative Detention Provision**

Coalition initial comments:

?? The coalition has not spent much time on this provision. There is no timeframe specified in the statute for this regulation. What is FDA's timeframe?

Bob Lake's initial comments:

?? We are planning on issuing a proposed rule that is on a comparable timeframe as the others.

?? This regulation is more for FDA actions. The agency does have experience with detentions in the device arena.

Leslye Fraser's initial comments:

?? There is no statutory deadline, but with the public outreach we plan on doing, we want to keep detention on a similar timeline as the others.

Industry: Two marking regulations were withdrawn this week, right?

Bob Lake: The import for export provision applies to all FDA-regulated products. The Bioterrorism Act changed the requirements for marking and so we had to withdraw the marking regulations that were currently being finalized.

Leslye Fraser: The import for export provision takes effect on 9/9/02. Guidance will be forthcoming on this provision. There is current discussion on whether there will be a regulation or guidance regarding the marking provision. The marking provision in administrative detention is different. In detention, the product is marked as being detained; with marking, it is marked as "U.S. Refused Entry."

Industry: Let us know if FDA needs more information.

Recorded by:

Denise R. Beavers and May Dimasin Nelson
Regulatory Counsels
Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration

**National Food Processors Association**
**Industry Coalition Meeting**
**Wednesday, August 28, 2002**
**1:30pm B 4:30pm**

## Attendees

1. Peggy Rochette (National Food Processors Association)
2. Patrick Donoho (International Bottled Water Association)
3. Bob Garfield (AFFI)
4. Gary Jay Kushner (Hogan & Hartson)
5. Sherry Marcouiller (Kraft Foods)
6. Annette Dickinson (CRN)
7. Elizabeth Wise Vaughan (Food Marketing Institute)
8. Justin LeBlanc (National Fisheries Institute)
9. Dave Dexter (SFA)
10. Lee Sanders (American Bakers Association)
11. Dan Herman (National Fisheries Institute)
12. Fred Hegele (General Mills, Inc.)
13. Mary Catherine Toker (General Mills, Inc.)
14. Mike Gill (American Frozen Food Institute)
15. Rick Cristol (The Kellen Company)
16. Melissa Scales (Center for Food Safety and Applied Nutrition)
17. Nega Beru (Center for Food Safety and Applied Nutrition)
18. Lloyd R. Lake (Center for Food Safety and Applied Nutrition)
19. May Nelson (Center for Food Safety and Applied Nutrition)
20. Marquita Steadman (Center for Food Safety and Applied Nutrition)
21. Amber Jessup (Center for Food Safety and Applied Nutrition)
22. Denise R. Beavers (Center for Food Safety and Applied Nutrition)
23. Susan Stout (GMA)
24. Stuart M. Pape (Patton Boggs)
25. Adam Witkonis (National Association of Convenience Stores)
26. Mike Mason (National Grocers Association)
27. Clay Detlefsen (IDFA)
28. Jennifer Snyder (Corn Refiners Association)
29. Jayna Gadomski (Cosmetic, Toiletry & Fragrance Association)
30. Ray Glowaky (Chocolate Manufacturing Association)
31. Bob Hahn (Olsson, Frank & Weeda)
32. Pat O'Connor (IWLA / Kent & O'Connor)
33. Rick Silverman (Hogan & Hartson)
34. Regina Hildwine (National Food Processors Association)
35. Nancy K. Cook (Pet Food Institute)

36. Stephen Payne (Pet Food Institute)
37. Randy Gordon (National Grain and Feed Association)
38. Richard Koby (National Coalition of Food Importing Associations)
39. Carolyn Brehm (Proctor & Gamble)
40. Chris Guay (Proctor & Gamble)
41. Mary Ayling (Center for Food Safety and Applied Nutrition)
42. Anne Taylor (Center for Food Safety and Applied Nutrition)
43. Leslye Fraser (Center for Food Safety and Applied Nutrition)